

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Brian A. Rosenfeld, M.D. and Michael Breslow, M.D.

Serial No.: 09/443,072 Group Art Unit: 2167

Filed: 11/18/99 Examiner: Harle, J.

For: **SYSTEM AND METHOD FOR PROVIDING CONTINUOUS, EXPERT
NETWORK CRITICAL CARE SERVICES FROM A REMOTE LOCATION(S)**

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AFFIDAVIT BY DR. RODNEY HOCHMAN

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I, Dr. Rodney Hochman, residing at 3301 Hidden Pointe Cove, Virginia Beach, VA 23452, state as follows:

1. I obtained my Medical degree in Medicine in 1979 from Boston University School of Medicine.
2. My experience includes twenty-three (23) years in Intensive Care Medicine at the locations listed on my CV.
3. My Curriculum Vitae is attached to provide further information regarding my background and qualifications that allow me to make the statements contained herein.
4. I have read and reviewed Patent Application Serial No.: 09/443,072 and the attached amended claim set.
5. I have read and reviewed the attached article "Intensive care unit telemedicine: Alternate paradigm for providing continuous care" from *Critical Care Medicine* 2000 Vol. 28, No. 12 by Rosenfeld et al.(the "Rosenfeld Study") describing the clinical study for which Dr. Rosenfeld was the Principal Investigator. I am familiar with the procedures described in this paper.
6. I believe the claimed invention is materially different from the Rosenfeld Study for at least the following reasons:
 - The claimed invention provides centralized monitoring of a plurality of geographically disparate ICUs by intensivists. In contrast the Rosenfeld Study monitored only

one single specialty 10-bed ICU. It is the capability of the claimed invention to allow a physician-led team, made up of intensive care specialists, critical care nurses and clerical support personnel (care team), to care for patients in multiple ICU's in disparate geographic locations, either within a building or in different buildings, simultaneously that creates new efficiencies and offers the potential to change the care paradigm for ICU patients. Thus, the expertise of the care team is leveraged over many ICU patients, who could not otherwise (without the claimed invention) be cared for by a single team.

- In contrast to the Rosenfeld Study where a single intensivist monitored faxed information, or initiated communication to view a single patient's bedside monitor over a personal computer, the claimed invention uses a computerized patient care management system that feeds key clinical information on multiple ICU patients simultaneously to the remote monitoring care team. The claimed invention includes imbedded decision support algorithms that further assist the care team in the continuous monitoring of large numbers of ICU patients. The claimed invention analyzes simultaneously all incoming patient physiologic data (from the bedside monitors) and laboratory data and provides visual alarms for the care team and alerts them to detrimental trends in patients vital signs and/or laboratory values that they might not be otherwise aware of. These features of the claimed invention allow a single physician-led team to care for patients in multiple, geographically disparate sites simultaneously. These features are totally lacking from the Rosenfeld Study and are not suggested by the study in any way.
- The claimed invention provides for 24-hour dedicated monitoring/management by a care team. The care team provides this service from a dedicated monitoring facility comprising equipment and decision support algorithms developed explicitly for this purpose. The claimed invention provides for automated warnings relating to vital signs and trends in vital signs, provides assessment of those trends for the intensivist, and makes recommendations for intervention available for consideration by the intensivist. The care team has no other care responsibilities during the time it is monitoring/managing the multiple geographically disparate ICU(s). The attention of the care team is devoted to the ICU patients and only the ICU patients.
- In contrast to the present invention, the Rosenfeld Study provided only 4-5 hours of ad hoc monitoring by a single intensivist from the intensivist's home (i.e. no continuous monitoring, no support personnel, and no dedicated facility). Further, the intensivist monitoring was not triggered in any automated way by any form of decision support algorithms, but was conducted periodically by the intensivist, as he deemed fit and time permitted. The intensivist in the Rosenfeld Study was solely responsible for analyzing the data, deducing trends in the patient's vital signs, assessing the meaning of the trends, and deciding on the corrective action to be taken - without access to any software tools to assist in these tasks. The software tools in the claimed invention create efficiencies that enable a single, intensivist-led team to monitor and care for large numbers of ICU patients.

7. I believe that remote, 24-hour intensivist-led care team monitoring of ICU patients in multiple geographically disparate locations is not taught by the Rosenfeld Study nor would one of skill in the art make the required changes to the equipment and procedures of the Rosenfeld Study to arrive at the present invention for at least the following reasons:

- Remote monitoring and direct intervention of ICU patients is contrary to prior accepted practice, where physicians are physically present in the ICU.
- The generally accepted medical monitoring paradigm in ICU's with intensivists on-staff is for the intensivists to conduct rounds with the staff, and for ICU nurses and other physicians to notify the intensivists of emergencies on an as-needed basis. The Rosenfeld Study subscribed to this generally accepted model of intensivist deployment in ICU's, daily rounds, periodic monitoring, and responding to requests for assistance from on-site personnel.
- The monitoring paradigm presently employed by hospitals is having lower-skilled bedside nurses perform this function. These personnel, with only bedside patient monitoring equipment and visual inspection, are relied on to make the decision to contact specialists, such as intensivists, when problems are detected.
- The invention described and claimed in Application Serial No.: 09/443,072 does not rely on the paradigm of primary monitoring by bedside personnel, with secondary calls to intensivist, but rather has the off-site intensivist-led care team provide continuous, 24-hour monitoring. The care team is capable of unilaterally entering the patient room for video and audio communication, and is supported by decision support algorithms that automatically alert the intensivist to detrimental trends in a patients' vital signs and facilitate the intensivist contacting the lower-skilled on-site personnel when interventions are necessary. Although the Rosenfeld Study included intensivist-initiated intervention through on-site physicians, the lack of 24-hour continuous monitoring illustrates that the prior art monitoring paradigm was still considered valid by those in the Rosenfeld Study.
- The Rosenfeld Study disclosed nothing of the technological nature disclosed in the claimed invention. Indeed the only way the intensivist had contact with the ICU and/or access patient data was for the intensivist to intermittently conduct active dial-up direct monitoring of the real-time bedside waveforms, request information by fax machine, or to telephonically contact an ICU nurse and have equipment (such as a video camera) physically moved to the desired patient location. None of this activity was in response to any system of automated notification to the intensivist and most required actions by on-site personnel.
- The technology tools that were developed in the current invention, such as smart alarms and physiologic data trend analysis, instantly available video monitoring from permanent camera installations in each ICU room, and comprehensive data links to command center, were not available at the time of the original clinical study nor was their use suggested in any way.

- The initial clinical study never addressed the potential for a single monitoring site for overseeing the care of patients in multiple ICU's thereby leveraging the expertise of an intensivist over a number of ICU's in geographically disparate locations.
- The original trial technology suite could not have been used over multiple ICU's in different geographic locations.
- At the time the clinical study it was unprecedented to have an intensivist functioning in a dedicated monitoring capacity and NOT attending to other functions.
- During the Rosenfeld study, an intensivist was required to monitor, on an ad-hoc basis, over a 24-hour shift. Continuous monitoring over such a long time period is too physically and mentally taxing to be feasible. In contrast, the system of the current invention allows for constant monitoring by an intensivist-led care team functioning on a normal 6-12 hour shift thereby alleviating both the physical and mental stress associated with a 24-hour shift.
- The Rosenfeld study was not the same model as that used in the present invention's model. The functioning of the current system constitutes an entirely different manner of monitoring multiple, geographically disparate ICU's than the clinical study which monitored but a single ICU without the analytical support offered in the present invention system.
- For a variety of licensing and clinical reasons, the clinical study was not a feasible model for hospital to use for ICU care. Individual hospitals would not have established intensivists at remote locations to monitor a single ICU at the hospital, having only the technology described in the study as a supporting infrastructure.
- When compared to the prior art standard of care, that is, an on-call intensivist responding to calls from on-site nurses, the results of using the present invention are remarkable, resulting in far better outcomes for ICU patients and far earlier intervention in life-threatening trends.

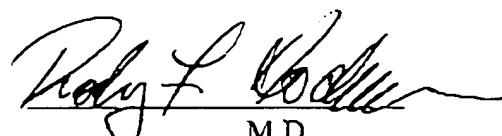
8. I believe that providing either a computerized patient care management system or a set of decision support algorithms to a remote care team (or a combination thereof) is not taught by the Rosenfeld Study, and neither the paper nor the standard practices of the time would suggest such a modification for at least the following reasons:

- The use of computerized patient care management systems at the time of the invention was limited, even in major hospitals, to the recording of patient data for later review by physicians, and to isolated on-site systems that sound an audible alarm when an extreme condition in a patient's vital signs is reached (i.e. cardiac arrest). Further, computerized decision support algorithms in the medical community were not available.

- When computerized patient care management systems are deployed by hospitals, they are provided at the bedside or ICU nursing stations. They are not provided remotely to a physician. Instead, physicians are contacted by a bedside nurse (via a "pager") to inform them that a problem has developed.
- Since the accepted wisdom of the medical community is to deploy patient care management systems and/or paper-based decision support for lower-skilled medical care givers on-site, there would be no reason to deploy these systems at a remote site for a care giver having the higher-skills of an intensivist.

9. The Rosenfeld Study evaluated the potential of "currently available technology" to "extend the effective reach of intensivists," but failed to disclose or suggest any of the additional technology of the presently claimed invention, such as (i) intensivist access to patient care management systems and/or decision support algorithms, that are required to effectively scale the monitoring to a greater number of patients and (ii) central command center monitoring that is required to effect a viable remote ICU monitoring model, (iii) monitoring of a plurality of geographically disparate healthcare locations/ICUs from a single remote command center, (iv) the use of a care team to enable monitoring and intervention on multiple patients in geographically different locations and (v) a data server/data warehouse for storing and analyzing data.

Date: 10/22/02



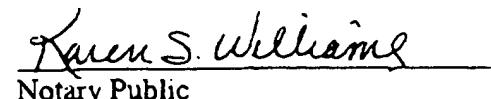
M.D.
Title
Affiliation

WITNESS MY HAND and seal this 22 day of October, 2002.

Rodney F. Hochman, MD
Type Name Here

STATE OF Virginia)
) ss:
COUNTY OF Norfolk)

On this 22 day of October, 2002 personally appeared before me in person to me known, and known by me to be the same person described in and who executed the foregoing instrument, and acknowledged that he executed the same, of his own free will and for the purposes set forth.


Notary Public

My Commission Expires: March 31, 2006

CURRICULUM VITAE

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PROFESSIONAL EXPERIENCE

SENTARA NORFOLK GENERAL HOSPITAL (Norfolk, VA) 2002 - Present
Administrator

SENTARA HEALTHCARE (Norfolk, VA) 1998 - Present
Chief Medical Officer & Senior Vice President

HEALTH ALLIANCE OF GREATER CINCINNATI (Cincinnati, OH) 1993 - 1998

Senior Executive Officer 1996 - 1998
Alliance Primary Care

CEO, Executive Director 1996 - 1998
Alliance Partners

Member, Board of Trustees 1996 - 1998
The Health Alliance of Greater Cincinnati

Medical Director and President 1994 - 1998
The Christ Hospital Medical Associates

Medical Director, Care Management Organization 1994 - 1998
The Christ Hospital

Volunteer Associate Professor of Medicine 1993 - 1998
University of Cincinnati College of Medicine

Treasurer 1996 - 1997
Alliance Physicians and Surgeons

Director, Department of Internal Medicine 1993 - 1996
The Christ Hospital

GUTHRIE HEALTH SYSTEM (Sayre, PA) 1984 - 1993

Member, Board of Directors	1992 - 1993
Guthrie Clinic	
Assistant Dean for Undergraduate and Graduate Education	1991 - 1993
Guthrie Healthcare System	
Director - Residency Program, Internal Medicine	1990 - 1993
Robert Packer Hospital	
Clinical Assistant Professor of Medicine	1989 - 1993
State University of New York, Health Science Center - Syracuse, NY	
Editorial Board	1988 - 1993
The Guthrie Journal	
Assistant Director - Residency Program, Internal Medicine	1988 - 1990
Robert Packer Hospital	
Associate - Rheumatology	1984 - 1993
Guthrie Clinic	
DARTMOUTH-HITCHCOCK MEDICAL CENTER (Hanover, NH)	1982 - 1984
Instructor - Clinical Medicine	1982 - 1984
Dartmouth Medical School	
Fellow - Department of Connective Tissue Diseases	
NEW ENGLAND DEACONESS HOSPITAL (Boston, MA)	1979 - 1982
Clinical Fellow - Internal Medicine	1979 - 1982
Harvard Medical School	

EDUCATION

Doctorate of Medicine - Boston University School of Medicine	1979
Summa Cum Laude, B.A. - Boston University	1975

POSTDOCTORAL TRAINING

Fellowship in Rheumatology	1982 - 1984
Dartmouth, Hitchcock Medical Center - Hanover, NH	
Residency in Internal Medicine	1980 - 1982
New England Deaconess Hospital - Boston, MA	
Internship in Internal Medicine	1979 - 1980
New England Deaconess Hospital - Boston, MA	

LICENSURE/CERTIFICATION

University of the State of New York	1985
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State Board of Medical Education and Licensure, Pennsylvania	1984
State Board of Ohio	1993
State Board of Virginia	1999

LICENSURE/CERTIFICATION (Continued)

Diplomate - American Board of Internal Medicine - Rheumatology	1984
Diplomate - American Board of Internal Medicine	1982
Diplomate - National Board of Medical Examiners	1980

MEMBERSHIPS/HONORS

Associate Member - Harvard Medical Alumni Association	
Fellow - American College of Physicians	
Fellow - American College of Rheumatology	
American College of Physician Executives	
Board Member - Comprehensive Health Investment Project (CHIP) of Virginia	2001
Medical Society of Virginia	2001
Member - American College of Healthcare Executives	2000
The Health Management Academy	2000
Board Member - National Chronic Care Consortium	1998
Physician Leadership Council - Voluntary Hospitals of America	
Teaching Award - Department of Medicine - Robert Packer Hospital	1987
James Tullis Award - Department of Medicine - Robert Packer Hospital	1982
Phi Beta Kappa	1979
Graduate, Summa Cum Laude - Boston University	1975

PUBLICATIONS

William HJ, Ward JR, Reading JC, Brooks RH, Clegg DO, Skosey JL, Weisman MH, Willkens RF, Singer JZ, Alarcon GS, Field EH, Clements PJ, Russell IJ, **Hochman RF**, Boumpas DT, Marble DA: Comparison of Auranofin, Methotrexate, and the combination of both in the treatment of rheumatoid arthritis. Arthritis and Rheumatism, Vol. 35, No. 3 (March 1992), pgs. 259-269.

Hwang J, Michaels RM, **Hochman RF**, Bartenhagen NH: The relationship of dermatomyositis to underlying malignancy. The Guthrie Journal, 60 (3) pg 101-105, Summer 1991.

Hochman, RF: Pulmonary vasculitis complicating Crohn's disease. The Guthrie Journal, 59 (3) pg 169-171, Summer 1990.

Michaels RM, Nashel DJ, Glickstein SL, **Hochman RF**, Finkelstein JD: Does Methotrexate treatment of rheumatoid arthritis cause acute transanization? The Guthrie Journal, 58 (3) 115-116, Summer 1989.

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O'Connor GT, Kwoh CK, Regan-Smith MG, Olmstead EM, Burnett JB, Hochman RF, King K, Mogan VG: Concordance Between Clinicians and Patient's Assessment of Physical and Mental Status. Abstract. Ninth Northeastern Regional Meeting. Toronto, Canada, October 1984.

PUBLICATIONS (Continued)

Hochman RF, Michaels RM: Autoantibodies in the Rheumatic Diseases. *The Guthrie Bulletin*, 54, (3) pg 129-136, Winter 1985.

Morgan, GJ, Hochman RF, Kwoh CK, Taylor T: Low Does Methotrexate in the Treatment of Rheumatoid Arthritis. Abstract, Tenth European Congress on Rheumatology, 1983.

Morgan, GJ, Hochman RF, Weider DJ: Cogan's Syndrome: Acute Vestibular and Auditory Dysfunction with Intestinal Keratitis. *Am J Otolaryngol*, 5:258-261, 1984.

Clark J, Hochman RF, Rolla AR, Thomas S, Miller DG : Coagulopathy Associated with the use of Cephalosporin or Moxalactam Antibiotics in Acute and Chronic Renal Failure. *Clin Exper Dialysis and Adpheresis*, 7(3), 177-190, 1983.

Hochman RF, et al : Bleeding in Patients with Infections. *Archives of Internal Medicine*, August, 1982.

RECENT PRESENTATIONS

The Health Management Academy (Arizona)..... October, 2001
Executive Grand Rounds - Sentara Healthcare-An Integrated Health System

National Physician Leadership Council (San Diego)..... August, 2001
eICU at Sentara Healthcare

VHA Leadership Conference (Los Angeles, CA)..... April, 2001
Creating Marketplace Advantage Through Strategic Physician Partnerships

General Assembly, State of Virginia (Richmond)..... January, 2001
Testimony on Certificate of Public Need (COPN)

VHA Physician Leaders Forum..... October, 2000
Panel on Evolving Strategies for Affiliating w/ Primary Care Physicians

U.S. House of Representatives Committee on Commerce September, 2000
*Testimony on National Physician Data Bank
(On Behalf of American Hospital Association)*

U. S. House of Representatives Commerce Committee March, 2000
*Testimony on National Physician Data Bank
(On Behalf of American Hospital Association)*

Healthcare 2004 (Chicago, IL) August, 1999
A Vision for the Future

American College of Radiology Summer Conference (Montreal)..... July, 1999
Service Line Management

VHA Physician Leaders Forum..... October, 1998
CEO/CMO Relationships